

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Group Art Unit 1617

8/16/17

In re Patent Application of

Charles W. Bishop, et al.

Application No. 09/753,697

Confirmation No.: 1609

Filed: January 3, 2001

Examiner: Theodore J. Criares

"24-HYDROXYVITAMIN D, ANALOGS
AND USES THEREOF"

I, Sally J. Sorensen, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of my signature.

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Signature

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PURSUANT TO 37 CFR §1.97(c)

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Sir:

The Examiner's attention is directed to the references which are listed on the attached Forms PTO/SB/08A and PTO/SB/08B, copies of which are attached. This Statement is also being accompanied by a check for \$180 in payment of the fee required under 37 CFR §1.17(p). Please charge or credit Deposit Account No. 50-0842 with any shortage or overpayment of the required fee. This paper submission is being filed simultaneously with an electronic IDS submission and both are considered to be part of the same, single IDS. Citation of these references is respectfully requested.

No concession is made that these documents are prior art, and Applicant expressly reserves the right to antedate the documents as may be appropriate.

03/17/2004 JBALINAH 00000096 09753697

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Respectfully submitted,

Jeffrey D. Peterson
Jeffrey D. Peterson
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File No. 17620-9316

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

1

of

5

Complete if Known

Application Number

09/753,697

Filing Date

January 3, 2001

First Named Inventor

Charles W. Bishop

Group Art Unit

1617

Examiner Name

Theodore J. Criares

Attorney Docket Number

017620-9316

MAR 15 2004

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.

AA	Barton, D. et al., "Synthetic Uses of Steroidal Ring & Diene Protection: 22,23-Dihydroergosterol," <i>JCS Perkin I</i> , (1976) pp. 821-826.
AB	Beer, T. et al., "Weekly High-Dose Calcitriol and Docetaxel in Metastatic Androgen-Independent Prostate Cancer," <i>Journal of Clinical Oncology</i> , (Jan. 2003) 21:1:123-128.
AC	Blazsek, I. et al. "Combined Differentiation Therapy in Myelodysplastic Syndrome with Retinoid Acid, 1 α ,25 Dihydroxyvitamin D ₃ , and Prednisone," 16:4:259-264 (Abstract).
AD	Brautbar, N. "Osteoporosis: Is 1,25-(OH)2D ₃ of Value in Treatment?" <i>Nephron</i> (1986) 44:161-166.
AE	Braunwald, E. et al., <i>Harrison's Principles of Internal Medicine</i> : Part Eleven, "Disorders of Bone and Mineral Metabolism," Chapter 335, McGraw-Hill, New York, (1987) pp. 1860-1865.
AF	Brown, J.P. et al., "Serum Bone Gla-Protein: A Specific Marker for Bone Formation in Postmenopausal Osteoporosis," <i>Lancet</i> , (1984) 1:1091-1093.
AG	Caniggia, A. et al., "Effect of a Long-Term Treatment with 1,25-Dihydroxyvitamin D ₃ on Osteocalcin in Postmenopausal Osteoporosis," <i>Calcified Tissue Int.</i> , (1986) 38:328-332.
AH	Christiansen, C. et al., "Prevention of Early Postmenopausal Bone Loss: Controlled 2-Year Study in 315 Normal Females," <i>Europ J Clin Inves.</i> , (1980) 10:273-279.
AI	Crump, D.R. et al., "(22S)-Hydroxyvitamin D ₄ ," <i>J.C.S. Perkins Trans. I</i> , (1973) pp. 2731-2733.
AJ	Cho, Y.L. et al., "Combined Effects of 1,25-Dihydroxyvitamin D ₃ and Platinum Drugs on the Growth of MCF-7 Cells," <i>Cancer Research</i> , (June 1991) 51:2848-2853.
AK	Defacque, H. et al., "Different Combinations of Retinoids and Vitamin D ₃ Analogs Efficiently Promote Growth Inhibition and Differentiation of Myelomonocytic Leukemia Cell Lines," <i>J. Pharmacology and Experimental Therapeutics</i> , (1994) 271:193-199.
AL	DeLuca et al., "Synthesis, Biological Activity, and Metabolism of 22,23- ³ H-Vitamin D ₄ ," <i>Arch. Biochem. Biophys.</i> , (1968) 124:122-128.
AM	Duda et al., "1,25-Dihydroxyvitamin D Stimulation Test for Osteoblast Function in Normal and Osteoporotic Postmenopausal Women," <i>J. Clin Inves.</i> , (1987) 79:1249-1253.
AN	Endo, K. et al., "Effect of Combination Treatment with Vitamin D Analog (OCT) and a Bisphosphonate (AHPBP) in a Nude Mouse Model of Cancer-Associated Hypercalcemia," <i>Journal of Bone and Mineral Research</i> , (1998) 13:9:1378-1383.
AO	Foldes, J. et al., "Long Term Treatment with 1 α (OH)D ₃ for Postmenopausal Osteoporosis: Efficacy and Safety," <i>Osteoporosis</i> , (1987) 2:971-973.

Examiner
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	09/753,697
				Filing Date	January 3, 2001
				First Named Inventor	Charles W. Bishop
				Group Art Unit	1617
				Examiner Name	Theodore J. Criares
Sheet	2	of	5	Attorney Docket Number	017620-9316

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.

AP	Gallagher, J.C. et al., "Effects of Increasing Doses of 1 α -Hydroxyvitamin D ₂ on Calcium Homeostasis in Postmenopausal Osteopenic Women," <i>J. Bone Min. Res.</i> , (1994) 9:5:607-614.
AQ	Grab, W. <i>Z. Physiol. Chem.</i> , (1936) 243:63-89.
AR	Guidelines for the Clinical Evaluation of Drugs Used in the Treatment of Osteoporosis, HEW (FDA) 80-3094, (1979) pp. 5-6.
AS	Hershberger, P. et al. "Calcitriol (1,25-Dihydroxycholecalciferol) Enhances Paclitaxel Antitumor Activity <i>in Vitro</i> and <i>in Vivo</i> and Accelerates Paclitaxel-induced Apoptosis," <i>Clinical Cancer Research</i> , (April 2001) 7:1043-1051.
AT	Hoikka, V. et al., "Treatment of Osteoporosis with 1-Alpha-Hydroxycholecalciferol and Calcium," <i>Acta. Med. Scand.</i> (1980) 207:221-224.
AU	Holick, M.F., "Noncalcemic Actions of 1,25-Dihydroxyvitamin D ₃ and Clinical Applications", <i>Bone</i> , (1995) 17:2:107S-110S.
AV	Horst et al., "Quantitation of Vitamin D and its Metabolites and Their Plasma Concentrations in Five Species of Animals," <i>Anal. Biochem.</i> , (1981) 116:189-203.
AW	Horst et al., "Discrimination in the Metabolism of Orally Dosed Ergocalciferol and Cholecalciferol by the Pig, Rat and Chick," <i>Biochem. J.</i> , (1982) 204:185-189.
AX	Johnson, C. et al., "Vitamin D-related Therapies in Prostate Cancer," <i>Cancer and Metastasis Review</i> 21, (2002) pp. 147-158.
AY	Kanis, J.A. et al., "Guidelines for Clinical Trials in Osteoporosis, A Position Paper of the European Foundation for Osteoporosis," <i>Osteoporosis Int.</i> , (1991) 1:182-188.
AZ	Kim, S. et al., "Potentiation of 1,25-Dihydroxyvitamin D ₃ -Induced Differentiation of Human Promyelocytic Leukemia Cells into Monocytes by Costunolide, a Germacranolide Sesquiterpene Lactone," <i>Biochem. Pharmacology</i> , (2002) 64:1233-1242.
BA	Knutson, et al., "Metabolism of 1 α -Hydroxyvitamin D ₂ to activated Dihydroxyvitamin D ₂ Metabolites Decreases Endogenous 1 α ,25-Dihydroxyvitamin D ₃ in Rats and Monkeys," <i>Endocrinology</i> , (1995) 136:11:4749-4753.
BB	Kocienski, P.J. et al., "Calciferol and its Relatives. A Synthesis of Vitamin D ₄ ," <i>J.C.S. Perkins I</i> , (1979) pp. 1290-1293.
BC	Londowski, J.M. et al., "Biological Activity of the C-1, C-3, C-25, β -D-Glucopyranosides of 1,25-Dihydroxyvitamin D ₃ ¹ ," <i>J. Pharmacology Expr. Ther.</i> , (1986) 237:3:837-840.

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				First Named Inventor	Charles W. Bishop
				Group Art Unit	1617
Examiner Name	Theodore J. Criares				
Sheet	3	of	5	Attorney Docket Number	017620-9316

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, pages(s), volume-issue numbers(s), publisher, city and/or country where published.
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BD	Majewski, <i>et al.</i> , "Inhibition of Tumor Cell-Induced Angiogenesis by Retinoids, 1,25-Dihydroxyvitamin D ₃ and their Combination," <i>Cancer Letters</i> , (1993) 75:35-39.
BE	Martin and DeLuca, "Calcium Transport," <i>Am. J. Physiol.</i> , 216:1352-1359.
BF	Mathias, C.J. et al., "Tumor-Selective Radiopharmaceutical Targeting Via Receptor-Mediated Endocytosis of Gallium-67-Deferoxamine-Folate," <i>J. Nucl. Med.</i> (1996), 37(6):1003-1008.
BG	McDonald, F.G., "The Multiple Nature of Vitamin D," <i>J. Biol. Chem.</i> 114, (1936) 1xv.
BH	<i>Merck Index</i> , S. Budavari (ed.), 11th ed., Merck & Co., Rahway, N.J. (1989) pp. 1579, #9930
BI	Moffatt, K. et al., "1 α ,25-Dihydroxyvitamin D ₃ and Platinum Drugs Act Synergistically to Inhibit the Growth of Prostate Cancer Cell Lines," <i>Clinical Cancer Research</i> , (March 1999) 5:695-703.
BJ	Muindi, J. et al., "Pharmacokinetics of High-Dose Oral Calcitriol: Results From a Phase 1 Trial of Calcitriol and Paclitaxel," <i>Clinical Pharmacology & Therapeutics</i> , (Dec. 2002) pp. 648-659.
BK	Nemeto, H. et al., "A Stereoselective Synthesis of 1 α - Hydroxy-Vitamin D ₃ ," <i>CHEMISTRY LETTERS</i> , (1985) 8:1131-1132.
BL	Paaren et al., "Direct C(1) Hydroxylation of Vitamin D ₃ and Related Compounds," <i>J. Org. Chem.</i> , (1980) 45:3253.
BM	Packman, K. et al. "Combination Treatment of MCF-7 Xenografts with the Vitamin D ₃ Analog EB1089 and Antiestrogens," (Vitamin D Endocrine Workshop, Nashville, TN May 27-June 1, 2000) pp. 511-514.
BN	Podenphant, J. et al., "Serum Bone Gla Protein and Other Biochemical Estimates of Bone Turnover in Early Postmenopausal Women During Prophylactic Treatment for Osteoporosis," <i>Acta Med Scand</i> , (1985) 218:329-333.
BO	<i>Physician's Desk Reference</i> , Edition 43:1746-1748.
BP	Pouilles, J.M. et al., "Prevention of Early Postmenopausal Bone Loss with 1 α -Hydroxy Vitamin D ₃ , A Three-Year Prospective Study," <i>Clin Rheumatol.</i> 11, 4 (1992) pp. 492-497.
BQ	Ravid, A. et al., "1,25-Dihydroxyvitamin D ₃ Enhances the Susceptibility of Breast Cancer Cells to Doxorubicin-induced Oxidative Damage," <i>Cancer Research</i> , (February 15, 1999) 59:862-867.
BR	Reeve, L.E. et al., "Biological Activity of 1 α -hydroxy Vitamin D ₂ in the Rat," <i>Arch. Biochem. Biophys.</i> (Feb. 1978) 186:1:164-167.
BS	Sato, F. et al., "Biological Activity of 1 α ,25-Dihydroxyvitamin D Derivatives - 24- <i>epi</i> -1 α ,25-Dihydroxyvitamin D-2 and 1 α ,25-Dihydroxyvitamin D-7," <i>Biochim. Biophys. Acta</i> , (1991) 1091:188-192.

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

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	BT	Siwinska, A. et al. "Potentiation of the Antiproliferative Effect <i>in Vitro</i> of Doxorubicin, Cisplatin and Genistein by New Analogues of Vitamin D," <i>Anticancer Research</i> , (2001) 21:1925-1929.
	BU	Sjoden et al., "Effects of 1 OHD ₂ on Bone Tissue," <i>Acta. Endocrinol.</i> (Copenh.) (Aug. 1984) 16:4:564-568.
	BV	Skowronski et al., "Vitamin D and Prostate Cancer: 1,25 Dihydroxyvitamin D ₃ Receptors and Actions in Human Prostate Cancer Cell Lines," <i>Endocrinology</i> , (1993) 132:1952-1960.
	BW	Slapak, C. et al., "Treatment of Acute Myeloid Leukemia in the Elderly with Low-Dose Cytarabine, Hydroxyurea, and Calcitriol," <i>Amer. J. Hematology</i> , (1992) 41:178-183.
	BX	Sommerfeldt et al., "Metabolism of Orally Administered [³ H]Ergocalciferol and [³ H]Cholecalciferol by Dairy Calves," <i>J. Nutr.</i> , (1983) 11:2595-2600.
	BY	Song, X.D. et al., "Bryostatin-1 and 1 α ,25-Dihydroxyvitamin D ₃ Synergistically Stimulate the Differentiation of NB4 Acute Promyelocytic Leukemia Cells," <i>Leukemia</i> , (1999) 13:275-281.
	BZ	Studzinski, G. et al., "Potentiation by 1- α ,25-Dihydroxyvitamin D ₃ of Cytotoxicity to HL-60 Cells Produced by Cytarabine and Hydroxyurea," <i>J. National Cancer Inst.</i> , (April 1986) 76:4:641-648.
	CA	Strugnelli et al., "Metabolism of a Cyclopropane-Ring-Containing Analog of 1 α -Hydroxyvitamin D ₃ in a Hepatocyte Cell Model," <i>Biochem. Pharm.</i> , (1990) 40:333-341.
	CB	Suzuki, Y. et al., "The Enhancement of the Chemotherapeutic Effects on Human Prostate Cancer Cell - The Combination with the Growth Factor Interaction Inhibitor (Suramin)," <i>Acta Urologica</i> (1993) 12:1215-1220, (Abstract).
	CC	Swami, S. et al. "1 α ,25-Dihydroxyvitamin D ₃ Down-Regulates Estrogen Receptor Abundance and Suppresses Estrogen Actions in MCF-7 Human Breast Cancer Cells," <i>Clinical Cancer Research</i> , (Aug. 2000) 6:3371-3379.
	CD	Tachibana, Y. (Nisshin Flour Milling Co.), "Preparation of 1Beta-Hydroxyvitamin D ₂ and D ₃ ," <i>CHEMICAL ABSTRACTS</i> , (1990) 113:1:6688 Col. 2 Abstract No. 6683y.
	CE	Tanaka, Y. et al., <i>Endocrinology</i> (1973) 92:417-422.
	CF	Torres, R. et al., "Etoposide Stimulates 1,25-Dihydroxyvitamin D ₃ Differentiation Activity, Hormone Binding and Hormone Receptor Expression in HL-60 Human Promyelocytic Cells," <i>Molecular and Cellular Biochemistry</i> , (2000) 208:157-162.
	CG	Tsuji, M. et al., "Synthesis of 22,23-Dihydro-1 α ,25-Dihydroxyvitamin D ₂ and its 24R-Epimer, New Vitamin D ₂ Derivatives," <i>Bull. Chem. Soc. Jpn.</i> , (1990) 63:8:2233-2238.

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CH	Wang, Q. et al., "1,25-Dihydroxyvitamin D ₃ and All-trans-Retinoic Acid Sensitize Breast Cancer Cells to Chemotherapy-induced Cell Death," <i>Cancer Research</i> , (April 2000) 60:2040-2048.
CI	Wang, X. et al., "Inhibition of p38 MAP Kinase Activity Up-Regulates Multiple MAP Kinase Pathways and Potentiates 1,25-Dihydroxyvitamin D ₃ -Induced Differentiation of Human Leukemia HL60 Cells," <i>Experimental Cell Research</i> , (2000) 258:425-437.
CJ	Wientroub, S. et al. "The Dichotomy in the Effects of 1,25 Dihydroxy Vitamin D ₃ and 24, 25 Dihydroxy Vitamin D ₃ on Bone Gamma-Carboxyglutamic Acid-Containing Protein in Serum and Bone in Vitamin D-Deficient Rats," <i>Calcif. Tissue Int.</i> , (1987) 40:166-172.
CK	Windaus, A. et al., "Uber das Krystallisierte Vitamin D ₄ ," <i>Z. Physiol. Chem.</i> , (1937) 247:185-188.
CL	Yu, W. et al., "Enhancement of 1,25- Dihydroxyvitamin D ₃ - Mediated Antitumor Activity with Dexamethasone," <i>J. National Cancer Inst.</i> , (January 1998) 90:2:134-141.
CM	Zerwekh et al., "Short-Term 1,25-Dihydroxyvitamin D ₃ Administration Raises Serum Osteocalcin in Patients with Postmenopausal Osteoporosis," <i>J. Clin. Endocrinol. Metabol.</i> , (1985) 60:615-617.

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ACKNOWLEDGEMENT RECEIPT**

Electronic Version 1.1

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**Title of
Invention**

24 HYDROXYVITAMIN D, ANALOGS AND USES THEREOF

Submission Type: Information Disclosure Statement

Application Number: 09/753697

*09/75

EFS ID: 56928

Server Response:

Confirmation Code	Message
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First Named Applicant: Charles Bishop

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ELECTRONIC INFORMATION DISCLOSURE STATEMENT

Electronic Version v18

Stylesheet Version v18.0

Title of Invention	24 HYDROXYVITAMIN D, ANALOGS AND USES THEREOF																																																																																
<div style="display: flex; justify-content: space-between;"> <div> <p>Application Number: 09/753697</p> <p>Confirmation Number: 1609</p> <p>First Named Applicant: Charles Bishop</p> <p>Attorney Docket Number: 0176209316</p> <p>Art Unit: 1617</p> <p>Examiner: Theodore J. Criares</p> <p>Search string: (2383446 or 3697559 or 3741996 or 4160803 or 4362710 or 4508651 or 4588716 or 4661294 or 4698328 or 4717721 or 4902481 or 5141719 or 5157135 or 5205989 or 5219528 or 5232836 or 5264184 or 5264618 or 5334740 or 5338532 or 5372996 or 5417923 or 5488120 or 5527524 or 5554386 or 5597575 or 5614513 or 5637742 or 5661025 or 5739271 or 5795882 or 6537982).pn.</p> </div> <div style="text-align: right;"> <p>*09/753697*</p> </div> </div>																																																																																	
<p>US Patent Documents</p> <p>Note: Applicant is not required to submit a paper copy of cited US Patent Documents</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th>init</th> <th>Cite.No.</th> <th>Patent No.</th> <th>Date</th> <th>Patentee</th> <th>Kind</th> <th>Class</th> <th>Subclass</th> </tr> </thead> <tbody> <tr><td></td><td>1</td><td>2383446</td><td>1941-06-04</td><td>Calcott et al</td><td></td><td></td><td></td></tr> <tr><td></td><td>2</td><td>3697559</td><td>1972-10-10</td><td>DeLuca et al.</td><td></td><td></td><td></td></tr> <tr><td></td><td>3</td><td>3741996</td><td>1973-06-26</td><td>DeLuca et al.</td><td></td><td></td><td></td></tr> <tr><td></td><td>4</td><td>4160803</td><td>1979-07-10</td><td>Potts</td><td></td><td></td><td></td></tr> <tr><td></td><td>5</td><td>4362710</td><td>1982-12-07</td><td>Watanabe</td><td></td><td></td><td></td></tr> <tr><td></td><td>6</td><td>4508651</td><td>1985-04-02</td><td>Baggiolini et al</td><td></td><td></td><td></td></tr> <tr><td></td><td>7</td><td>4588716</td><td>1986-05-13</td><td>DeLuca et al</td><td></td><td></td><td></td></tr> <tr><td></td><td>8</td><td>4661294</td><td>1987-04-28</td><td>Holick et al</td><td></td><td></td><td></td></tr> <tr><td></td><td>9</td><td>4698328</td><td>1987-10-06</td><td>Neer et al</td><td></td><td></td><td></td></tr> </tbody> </table>		init	Cite.No.	Patent No.	Date	Patentee	Kind	Class	Subclass		1	2383446	1941-06-04	Calcott et al					2	3697559	1972-10-10	DeLuca et al.					3	3741996	1973-06-26	DeLuca et al.					4	4160803	1979-07-10	Potts					5	4362710	1982-12-07	Watanabe					6	4508651	1985-04-02	Baggiolini et al					7	4588716	1986-05-13	DeLuca et al					8	4661294	1987-04-28	Holick et al					9	4698328	1987-10-06	Neer et al			
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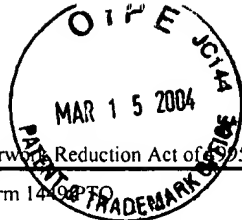
Remarks

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Examiner Name	Date



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 1 of 1				Complete if Known	
				Application Number	09/753,697
				Filing Date	January 3, 2001
				First Name Inventor	Charles W. Bishop
				Group Art Unit	1617
				Examiner Name	Theodore J. Criares
				Attorney Docket Number	017620-9316

U.S. PATENT DOCUMENTS

Examiner Initials	U.S. Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document

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FOREIGN PATENT DOCUMENTS

Examiner Initials	Country Code	Foreign Patent Document Number	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Translation	English Abstract
	Belgium	877 356	Wisconsin Alumni Research Foundation	10/15/79		
	Japan	5320127	Nisshin Flour Milling Co.	09/29/93		
	Japan	6025039	Kurary Co. Ltd.	02/01/94		
	Japan	62000033	General Hospital	10/15/86		
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	PCT	WO 84/04527	Wisconsin Alumni Research Foundation	11/22/84		
	PCT	WO 87/00834	Leo Pharmaceutical Products, Ltd.	02/12/87		
	PCT	WO 90/10620	Wisconsin Alumni Research Foundation	09/20/90		
	PCT	WO 92/21355	Procter & Gamble	12/10/92		
	PCT	WO 93/07883	ISIS Pharmaceuticals	04/29/93		
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